PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	John Chen
Application No.:	09/689,139
Filed:	October 12, 2000
For:	SciMed Life Systems, Inc.
Examiner:	Sandra M. Nolan
Group Art Unit:	1772

Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-9178

DECLARATION UNDER 37 C.F.R. §1.132

I, Paul J. Miller, attest and say as follows:

1. I, Paul J. Miller, have been employed by SCIMED Life Systems, Inc., now Boston Scientific SCIMED since February of 1991. I have a Masters of Science in Manufacturing Systems from the University of St. Thomas and a Bachelor of Science in Material Science Engineering from the University of Minnesota, Institute of Technology. I have been involved in balloon component development and related balloon catheter development for over 12 years. My current position is Research & Development Director of Catheter Product Development. My responsibilities as Director include managing the department which designs catheter balloons. From July, 2000 to November, 2002 my position was Polymer Materials R&D Manager where I managed research and development work for polymer based designs and technologies for balloon catheters. From July, 1999 to July, 2000 I was the Balloon Catheter Research & Development manager. My responsibilities included, among others, managing balloon catheter development projects and supervising team leaders. From August, 1997 to August 1999, I was the Cardiology Product Development Manager for Boston Scientific Ireland. From October, 1995 to August, 1997 I was the a project engineer. In this capacity, I acted as a

team leader and was the Research & Development engineer responsible for the development of a high pressure balloon catheter. From October, 1993 to October, 1995, I was an Engineering Supervisor for Balloon Process Development. In this capacity, I supervised a technical staff responsible for developing processes used to manufacture polymer components. From February, 1991 to October, 1993, I was a process development engineer responsible for managing balloon component pilot products. Responsibilities included overseeing balloon component builds for FDA submissions and problem solving for production issues.

2. I am also the co-inventor of a number of patents related to balloon catheters including U.S. 5,714,110; U.S. 6,045,547; and U.S. 6,328,710 as well as eight currently pending patent applications.

3. Based on my extensive experience in the area of balloon catheters and specifically in the area of the inflatable balloon component thereof, I am qualified as one skilled in the art of balloon catheter design and commercially available balloon catheter models and the inflatable balloon component thereof.

4. I provide this Declaration in support of the patentability of the subject matter disclosed and claimed in the patent application which is referenced above.

5. Inflatable balloons are typically sterilized with ethylene oxide gas at a temperature of 45° to 50° C. I have read and understand Fritz et al., US 5735830. Fritz et al. describes steam sterilization at a temperature of 134° C. Fritz et al. describe medical instruments like catheters, tubes, tracheal tubes, and the like. In contrast to such tubes, balloons are very thin walled, delicate structures. Based on my knowledge and experience, it is my opinion that formation of a balloon followed by steam sterilization is a process which would not be followed in the balloon forming art. Balloons are not steam sterilized after formation because the temperature required has a negative impact on the physical properties of the balloon. In fact, after steam sterilization, most balloons would shrink to such a degree that they would no longer have utility as such. Thus, first

forming a balloon and then steam sterilizing it is not a practice which is followed in the art.

I have also read and understand Wang et al., US 5348538. Wang et al. describe a final annealing process in the formation of a balloon catheter in which the balloon catheter is submerged in water or air at a temperature in the range of 25° to 100° C for 3-180 minutes with a preferred temperature range of 65° to 80° C. The annealing process causes the length and the diameter of the balloon to decrease and the wall thickness to increase. After the balloon catheter has been removed from the annealing process it is sterilized under ethylene oxide at 47° C (Col. 11, lines 47-59). Thus, the conditions described in Wang et al. for shrinking the balloon are in no way analogous to the conditions of steam sterilization described in Fritz et al. and in fact, Wang et al. describe ethylene oxide sterilization of the balloon at a temperature of 47° C which is considerably lower than 134° C as specified by Fritz et al. Consequently, Wang et al. does not provide suggestion or motivation to steam sterilize a balloon.

There is no specific suggestion by Fritz et al. that such materials would have the properties optimal for successfully making balloon catheters.

All statements made herein of my own knowledge are true; all statements made on the information and belief are believed to be true; and all the foregoing statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application and any registration resulting therefrom.

Date: 3/24/03

Signed: Paul J. Miller

Paul J. Miller